IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA

AbbVie Inc. (a Delaware corporation); Allergan, Inc. (a Delaware corporation); Durata Therapeutics, Inc. (a Delaware corporation); AbbVie Products LLC (a Georgia limited liability company); Aptalis Pharma US, Inc. (a Delaware corporation); Pharmacyclics LLC (a Delaware limited liability company); Allergan Sales, LLC (a Delaware limited liability company), *Plaintiffs*, v. JEFFREY LANDRY, in his official capacity as the Attorney General of the State of Louisiana, *Defendants*.	No. 6:23-CV-01307 **FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Aptalis Pharma US, Inc., Pharmacyclics LLC, Allergan Sales, LLC (collectively "AbbVie" or "Plaintiffs"), by and through their undersigned attorneys, bring this action for declaratory and injunctive relief against the Attorney General of the State of Louisiana challenging the constitutionality of "The Defending Affordable Prescription Drug Costs Act," referred to as Louisiana Act 358. In support, AbbVie alleges as follows:

PRELIMINARY STATEMENT

1. AbbVie brings this lawsuit to challenge the constitutionality of Act 358. Act 358 conflicts with federal law by impermissibly adding state law requirements for participating in the

federal drug discount program established under Section 340B of the Public Health Service Act (the "340B statute") in violation of the Supremacy Clause of the United States Constitution.

2. The federal 340B statute establishes a comprehensive program that is designed to help uninsured and low-income patients gain better access to prescription medications at discounted prices. As a condition of participating in the federal Medicaid program, participating pharmaceutical manufacturers must offer their covered outpatient drugs at deeply discounted prices to an enumerated list of "covered entities"—certain registered and specially identified safety net hospitals and clinics—that are expected to serve vulnerable patient populations. *See* 42 U.S.C. § 256b(a)(4). Federal law thus imposes an obligation on manufacturers to provide their drugs at 340B discounted prices to certain specified covered entities in exchange for the federal government's commitment to subsidize Medicaid beneficiaries' drug expenses. Contract pharmacies are not mentioned in—let alone required by—the federal 340B statute.

3. The federal statute grants the Secretary of the U.S. Department of Health and Human Services ("HHS") exclusive authority to enforce its provisions. *See* 42 U.S.C. § 256b(d). The statute leaves no role for states or other third parties to change the requirements of the federal 340B program or the conditions it imposes on manufacturers in return for participating in Medicaid. Nor do states or other third parties have any authority to enforce the federal statute's requirements. The Supreme Court has held that third-party enforcement "would undermine the agency's efforts to administer" the 340B program and other related federal programs "harmoniously and uniformly." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 119–20 (2011).

4. Because forcing manufacturers to transfer their drugs at discounted prices to covered entities raises serious constitutional concerns, Congress carefully limited the program to ensure that manufacturers' discounted drugs would be used to help needy patients, and enacted

certain safeguards to prevent the program from being abused for the benefit of other private parties. For example, in a statutory provision designed to prevent "diversion," Congress made clear that covered entities are not allowed to transfer manufacturers' drugs to anyone other than their own patients, prohibiting other entities from either participating in the 340B program or profiting from the sale of manufacturers' drugs at the 340B discounted price. *See* 42 U.S.C. § 256b(a)(5)(B).

5. Nevertheless, over the last decade covered entities have entered into novel contractual arrangements with commercial pharmacies (called "contract pharmacies") that have allowed those pharmacies to profit from the sale of manufacturers' drugs. Instead of serving the covered entities' uninsured and low-income patients, the for-profit contract pharmacies acquire manufacturers' drugs at the federally discounted price, sell them to patients (including indigent patients) at full price, and pocket the difference. Contract pharmacies accomplish this arbitrage through a complicated accounting system known as the "replenishment model," described in more detail below. The bottom-line result is that for-profit commercial pharmacies and the covered entities they contract with are able to pocket billions of dollars every year, splitting the profits at the expense of both manufacturers and the needy patients who are supposed to be served by the federal 340B program.

6. Neither contract pharmacies nor the replenishment model are features of the ordinary commercial drug-distribution system in the United States, outside the 340B context, where they are unauthorized by statute. AbbVie is involved in no other commercial arrangement using contract pharmacies or the replenishment model. Contract pharmacies and the replenishment model are creatures only of the federal 340B drug discount arbitrage regime.

7. In response to these abuses, manufacturers (including AbbVie) have adopted policies that limit when they will sell or facilitate the transfer of drugs at the 340B discounted price

to third-party commercial pharmacies. These policies recognize that the federal statute requires only that manufacturers "offer" their drugs at discounted prices to the covered entities *themselves*. There is no additional requirement that manufacturers deliver the drugs to whomever and wherever the covered entities may demand, and there is certainly no requirement that manufacturers allow commercial pharmacies to *profit* from the sale of their drugs at discounted prices under the federal 340B program.

8. Manufacturers' decisions to address these abuses resulted in litigation between manufacturers and the U.S. Department of Health and Human Services and, in early 2023, the U.S. Court of Appeals for the Third Circuit confirmed that the manufacturers' policies are lawful and permitted under federal law. Congress required manufacturers to offer their covered outpatient drugs at discounted prices in return for participating in Medicaid; it did not impose any additional obligation on manufacturers to deliver their drugs to third-party commercial pharmacies, or to otherwise support arbitrage of their charitable discounts. Commercial pharmacies are not covered entities, and they are not entitled to benefit from the federal 340B program or access manufacturers' drugs at the 340B discounted price. *See Sanofi Aventis U.S. LLC v. U.S. Dept. of Health & Human Servs.*, 58 F.4th 696, 2023 WL 1098017 (3d Cir. Jan. 30, 2023).

9. Louisiana, through Attorney General Landry, participated in the Third Circuit case as an *amicus curiae*, on the losing side. About two months after that loss, the Louisiana Legislature began considering what eventually became Act 358, which attempts to impose requirements under the federal 340B statute that Congress chose not to impose.

10. In particular, Act 358 seeks to change the requirements of when and to which entities manufacturers must provide 340B discounted drugs as a condition of participating in Medicaid. *See* La. Rev. Stat. § 40:2884(A). Without defining "interference," Act 358 broadly

prohibits manufacturers and distributors from "interfer[ing]" with a commercial pharmacy that has contracted with a 340B covered entity. La. Rev. Stat. § 40:2884(A). It further prohibits manufacturers and distributors from "interfer[ing] with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity[.]" La. Rev. Stat. § 40:2884(B).

11. Act 358 violates the United States Constitution and should be enjoined.

12. ***First***, Act 358 is preempted by federal law under the Supremacy Clause. "The doctrine of federal preemption that arises out of the Supremacy Clause requires that 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.'" *Aldridge v. Mississippi Dep't of Corr.*, 990 F.3d 868, 874 (5th Cir. 2021) (quoting *Felder v. Casey*, 487 U.S. 131, 138 (1988)). By seeking to change the requirements of when and to which entities manufacturers must offer drugs at a discounted price as a condition of participating in the federal Medicaid program, Act 358 unlawfully modifies the requirements of the federal 340B program. Act 358 impermissibly injects the Attorney General of Louisiana, armed with state law penalties and other remedies, into what Congress intended to be an exclusively federal scheme. Act 358 also conflicts with the objectives of the 340B statute, imposing requirements on drug manufacturers that conflict with the actual requirements of the 340B statute, thereby raising the costs of Medicaid participation above those set by Congress and deterring manufacturers from that participation.

13. ***Second***, to the extent it is not preempted, Act 358 deprives manufacturers of property without due process of law and results in an impermissible taking under the Fifth Amendment. Under the Fifth Amendment, neither the federal government nor the states have any authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo*

v. City of New London, 545 U.S. 469, 477 (2005) (explaining that "the sovereign may not take the property of A for the sole purpose of transferring it to another private party B, even though A is paid just compensation"). The federal government has defended the federal 340B statute on grounds that manufacturers are not being *forced* to transfer their property to for-profit pharmacies, but instead supposedly agreed to do so at the request of covered entities "voluntarily" in exchange for the benefit of participation in the federal Medicaid program.

14. Louisiana, however, purports to directly require manufacturers to transfer their property to other private entities if those entities have *third-party* contracts that purport to allow them to access AbbVie's drugs at deep discounts. Louisiana has no authority to take private property for private use, and no authority to deprive AbbVie of its property without due process of law. By seeking to change the requirements for when drug manufacturers must provide and deliver 340B price drugs to contract pharmacies at the request of covered entities, the statute unlawfully appropriates private property for the private benefit of commercial pharmacies and does so without serving any valid public purpose. *See Horne v. Dep't of Agric.*, 576 U.S. 350, 370 (2015) (holding government's confiscation of portion of farmers' raisin crop for charitable or other purpose without just compensation was a *per se* taking).

15. ***Third***, Act 358 deprives manufacturers of property without due process of law and results in an impermissible taking under Article 1, Section Four of the Louisiana Constitution. Under Section 4 of the Louisiana Constitution, property may not be taken or damaged by the state or its political subdivisions for predominant use by any private person or entity, or for the transfer of ownership to any private person or entity. La. Const. Ann. art. I, § 4. The Office of the Attorney General has further emphasized that the Louisiana Legislature intended Section 4, among other laws, to generally prohibit the taking of property and selling it to private interests. La. Att'y Gen.

Op. No. 07-0147 (June 14, 2007). Louisiana attempts to take private property and transfer it to a private third-party without the due process of law, and in doing so, violates the Louisiana Constitution.

16. ***Fourth***, in the alternative, if Act 358 is not preempted and does not effect an impermissible taking, then Act 358 is unconstitutionally vague. "It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972) (collecting authority). "A law is unconstitutionally vague if it (1) fails to provide those targeted by the statute a reasonable opportunity to know what conduct is prohibited, or (2) is so indefinite that it allows arbitrary and discriminatory enforcement." *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411, 421 (5th Cir. 2001). The provisions of Act 358 that prohibit manufacturers from "interfering" with contract pharmacies provide no fair warning as to what conduct (or perhaps even speech) is actually prohibited, and manufacturers are instead left to guess at its meaning.

17. AbbVie seeks a declaration that Act 358 is unconstitutional because it is preempted by federal law. In the alternative, AbbVie seeks a declaration that Act 358 constitutes an unconstitutional taking or is unconstitutionally vague. AbbVie further seeks injunctive relief barring the Louisiana Attorney General from enforcing Act 358 against AbbVie.

PARTIES TO THE ACTION

18. AbbVie, Inc., a Delaware Corporation, is a global research-based biopharmaceutical company dedicated to addressing some of the world's most complex and serious diseases, and advancing medical science in areas such as immunology, oncology, and neuroscience. Since 2012, AbbVie, Inc. has participated in the federal 340B drug discount program, helping uninsured and vulnerable patients obtain access to the medications they need.

AbbVie's headquarters are located in North Chicago, Illinois. AbbVie, Inc. is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340 Pharmaceutical Pricing Agreements, with HRSA.

19. Allergan, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340 Pharmaceutical Pricing Agreements, with HRSA.

20. Durata Therapeutics, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340 Pharmaceutical Pricing Agreements, with HRSA.

21. AbbVie Products LLC, a Georgia Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340 Pharmaceutical Pricing Agreements, with HRSA.

22. Aptalis Pharma US, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340 Pharmaceutical Pricing Agreements, with HRSA.

23. Pharmacyclics LLC, a Delaware Limited Liability Company, is a new party to this lawsuit, and a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340 Pharmaceutical Pricing Agreements, with HRSA.

24. Previously, Warner Chilcott Corporation merged with Allergan Sales, LLC and Allergan Sales, LLC is the surviving entity. Allergan Sales, LLC, a Delaware Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340 Pharmaceutical Pricing Agreements, with HRSA.

25. Defendant Jeffrey Landry is the Attorney General of the State of Louisiana. In that role, he has the responsibility and authority to enforce the laws of the State of Louisiana, including Act 358, which makes any violation a violation of the state's Unfair Trade Practice and Consumer Protection Law. *See* La. Rev. Stat. § 40:2885. The Attorney General also has enforcement authority over violations of the Unfair Trade Practice and Consumer Protection Law. *See* La. Rev. Stat. §§ 51:1407-1408. This suit is brought against him solely in his official capacity.

JURISDICTION AND VENUE

26. AbbVie's causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution.

27. The Court has subject matter jurisdiction under 28 U.S.C. § 1331, 28 U.S.C. § 1332, and 28 U.S.C. § 1343(a)(3).

28. The Court has authority to grant injunctive and declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and the Court's inherent equitable powers, including the power to enjoin the actions of state officials if contrary to the United States Constitution or federal law. *See Ex parte Young*, 209 U.S. 123, 159–60 (1908).

29. Venue is proper in this district under 28 U.S.C. § 1391(b) because this action challenges a Louisiana law that is applicable to AbbVie's sale and distribution of drugs at discounted prices under the federal 340B statute within this district. AbbVie sells and distributes drugs to multiple 340B covered entities within this District, and these entities purport to maintain contract pharmacy arrangements. Venue is also proper because the Defendant maintains offices, through which he would enforce the challenged law, in the cities of Alexandria, Lafayette, Monroe, and Shreveport within this District.

GENERAL ALLEGATIONS

A. The 340B Drug Pricing Program

30. This case concerns section 340B of the federal Public Health Service Act, which created the federal "340B program" as part of the authority granted in the Veterans Health Care Act of 1992. *See* 42 U.S.C. § 256b; *see also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

31. The purpose of the federal 340B program is to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve" by creating "a low-cost source of pharmaceutical medication for the indigent patients themselves." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 638 (2015) (footnote omitted).

32. Before Congress created the 340B program, individual manufacturers voluntarily provided their drugs at reduced prices to institutions that served needy and vulnerable patients. In 1990, Congress passed a statute called the Medicaid Rebate Act, which had the unintended consequence of creating disincentives for manufacturers to continue providing those voluntary discounts. H.R. Rep. No. 102-384, pt. 2, at 9–10 (1992). Through the Veterans Health Care Act, Congress remedied that unintended disincentive and established the federal 340B program, turning the manufacturers' previous voluntary support into a federal mandate.

33. The 340B statute requires that any manufacturer that participates in the federal Medicaid Drug Rebate Program must "offer" its covered outpatient drugs "for purchase" at deeply discounted prices to eligible "covered entities"—disproportionate share hospitals and other service providers that are expected to serve predominantly low-income and vulnerable patients. 42 U.S.C. § 256b(a)(1).

34. The statute expressly limits participation in the 340B program to "covered entities." *See* 42 U.S.C. § 256b(a)(4). The statute defines "covered entities" to include only organizations that predominantly serve low-income patients. The definition includes, for example, federally qualified health centers, children's hospitals, qualifying rural hospitals, and clinics that serve vulnerable patients. *Id*. For-profit commercial pharmacies are not included in the statutory list of "covered entities." *Id*. § 256b(a)(4). Nor does the 340B statute include any provision authorizing covered entities to purchase manufacturers' drugs and dispense them through commercial pharmacies. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021) ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication."), *aff'd sub nom. Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703 (3d Cir. 2023).

35. The discounted 340B price for each of the manufacturer's drugs is calculated by subtracting the drug's Medicaid unit rebate amount from its Average Manufacturer Price, as determined under the federal Medicaid Drug Rebate Program, codified at section 1927 of the Social Security Act. *Id.* § 256b(a)(1)–(2) & (b). The resulting prices, called the 340B "ceiling prices," are significantly lower than the prices at which manufacturers sell their products to other purchasers. For the vast majority of innovator drugs, the mandatory discounts range from at least 23.1% to more than 99.9% of the average price in the market. *See* 42 U.S.C. § 1396r-8(c); 42 U.S.C. § 256b(a)(1). Many mandatory 340B ceiling prices are as little as one penny per unit of drug.

36. To indicate their agreement to participate in the federal 340B program and comply with its requirements, manufacturers sign a form contract with HHS, called the Pharmaceutical Pricing Agreement. That agreement is drafted by HHS. It has "no negotiable terms," and it

"incorporate[s] the statutory obligations and record[s] the manufacturers' agreement to abide by them." *Astra*, 563 U.S. at 117–18.

37. The Pharmaceutical Pricing Agreement imposes no obligation on participating manufacturers to sell discounted drugs to contract pharmacies. Nor does the Pharmaceutical Pricing Agreement require manufacturers to cause their discounted drugs to be transferred to contract pharmacies. Nor does it grant covered entities any right to obtain access to manufacturers' drugs at discounted prices through contract pharmacies.

38. Both the Pharmaceutical Pricing Agreement and the federal 340B statute are structured to prevent commercial parties from participating in the federal 340B program or profiting from the sale of manufacturers' drugs at discounted prices. Over the past decade, however, that is exactly what has happened as a result of covered entities entering into contractual relationships with commercial pharmacies. Under these arrangements, instead of using manufacturers' deeply discounted drugs to treat the indigent and uninsured patients that visit a covered entity and receive healthcare services from the covered entity itself, commercial contract pharmacies sell manufacturers drugs at regular prices to pharmacy customers and then demand that their stocks be replenished with drugs purchased by the covered entity through the federal 340B program at discounted prices, pocketing the difference (the "spread") for their own financial benefit.

39. In recent years, commercial contract pharmacies have earned annually over $3.3 *billion* in "spread." *See Eric Percher et al., Nephron Research LLC*, The 340B Program Reaches a Tipping Point: Sizing Profit Flows and Potential Disruption (2020)) (concluding that $3.348 billion in 340B discounts were retained as profit by contract pharmacies in 2020 alone).

40. These abuses of the federal 340B program raise obvious concerns because the U.S. Constitution prohibits the government from forcing the transfer of property at confiscatory prices to private parties for their own private benefit. *See* U.S. Const. amend. V. They also violate the letter and spirit of the federal 340B statute. Congress designed the 340B statute with the intent that there would be a close nexus between the federal drug pricing program and its only valid public purpose—helping low-income and uninsured patients obtain access to medications at discounted prices. Consistent with that intent, the statute prevents covered entities from using manufacturers' drugs to generate commercial profits or letting the drugs be transferred or sold to benefit entities outside the program.

41. The statute expressly forbids "diversion" by prohibiting covered entities from selling or otherwise transferring any manufacturer's discounted drugs "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity").

42. The statute also prohibits covered entities from receiving or causing "duplicate discounts or rebates." They may not obtain a 340B discount and cause a Medicaid rebate to be paid by the manufacturer for the same unit of drug. *Id.* § 256(a)(5)(A).

43. The statute imposes an affirmative duty on the Secretary of HHS—through authority delegated to HRSA—to protect the program's integrity by "provid[ing] for improvements in compliance by covered entities . . . in order to prevent diversion" and violations of the statute's duplicate discount prohibition. *Id.* § 256b(d)(2)(A).

44. The statute provides mechanisms for resolving administrative disputes between manufacturers and covered entities through audits and a federal Administrative Dispute Resolution ("ADR") process. *See* 42 U.S.C. § 256b(d)(l)(B)(v), (d)(3).

45. The statute entrusts enforcement of the 340B statute *exclusively* to the Secretary of HHS and details what penalties may apply. *See* 42 U.S.C. § 256b(a)(5)(C)–(D), (d)(l)(B)(v), (d)(3). As the Supreme Court reasoned in *Astra*, Congress made HHS administrator of both the Medicaid Drug Rebate Program and the 340B program, and private enforcement by covered entities "would undermine the [HHS's] efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Astra*, 563 U.S. at 119–20.

46. The 340B statute provides no private right of action to covered entities. *Id.* at 113–14.

47. Failure to comply with the statutory requirements under the 340B program may result in termination of the Pharmaceutical Pricing Agreement (and the manufacturer's ability to participate in Medicaid), federal enforcement actions, and potentially the imposition of large civil penalties. *See id.* § 256b(a)(5)(D), (d)(1)(B)(vi), (d)(2)(B)(v), (d)(3)(A).

B. The Growth in Contract Pharmacy Arrangements

48. In 1996, HRSA issued non-binding guidance stating that the agency would not prevent covered entities *that lacked an in-house pharmacy* from entering into a contractual relationship with a *single* outside pharmacy to dispense covered outpatient drugs to the covered entity's patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996). The guidance made clear that it "create[d] no new law and create[d] no new rights or duties." *Id.* at 43,550.

49. Guidance documents, such as the 1996 guidelines, are by definition general statements of policy that are non-binding, non-enforceable, and do not create any legal rights or

obligations. They are intended instead to inform the public as to how HRSA intends to exercise its enforcement discretion.

50. In 2010, HRSA issued new non-binding guidance that radically changed how covered entities operated under the 340B program. The guidance stated, for the first time, that the agency would allow covered entities to enter into contractual relationships with an *unlimited* number of "contract pharmacies," even if the covered entity had an in-house pharmacy of its own. 74 Fed. Reg. 10,272 (Mar. 5, 2010).

51. Like the 1996 guidance, the 2010 guidance did not impose binding obligations on manufacturers. Indeed, HRSA again made clear that the non-binding guidance created no new rights and imposed no new obligations. *See id.* at 10,273 ("This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law"). In other words, while HRSA indicated that it would not interpret the 340B statute to prohibit covered entities from using multiple contract pharmacies, it did not purport to impose any obligation on manufacturers to transfer drugs to contract pharmacies or otherwise facilitate covered entities' use of contract pharmacies.

52. Following issuance of the 2010 guidance, covered entities dramatically increased their use of contract pharmacies, with a recent study reporting an increase of 4,228% between 2010 and 2020. This explosion in the use of contract pharmacies has been driven by the prospect of sharing in the outsized profit margins on manufacturer-subsidized 340B drugs.

53. Contract pharmacies, which are predominantly large commercial pharmacy chains, do not operate like in-house pharmacies, do not themselves qualify as covered entities, and do not owe fiduciary duties to the covered entities. The relationships between covered entities and the for-profit, commercial pharmacies are governed by arm's-length contracts. Contract pharmacies

are not "agents" of the covered entities; they are merely business partners. Importantly, these arrangements do not exist outside the context of the federal 340B program, as there is no other context in which commercial pharmacies are able to share in the "spread" generated by selling manufacturers' discounted drugs to their customers at full prices.

54. Contract pharmacy arrangements generally use one of two inventory models: (1) pre-purchased inventory or (2) replenishment.

55. A few contract pharmacies use the pre-purchased inventory model, in which a covered entity's 340B purchased drugs are kept in stock at the contract pharmacy, and when filling prescriptions on behalf of that covered entity, the contract pharmacy uses the covered entity's 340B purchased inventory.

56. Most contract pharmacies, however, use what is known as the "replenishment" model. Under the replenishment model, no 340B purchased drugs are kept in stock at the contract pharmacy. Instead, the contract pharmacy fills all prescriptions using its own non-340B purchased inventory (that is, full price inventory)—including those prescriptions issued by covered entities. After a sufficient quantity of a particular drug is dispensed, the covered entity orders additional quantities of that drug at the federal 340B price be transferred and delivered to the contract pharmacy to "replenish" the non-340B drugs dispensed by the contract pharmacy on the covered entity's behalf. *See* Declaration of RADM Krista M. Pedley, Director, Office of Pharmacy Affairs, HRSA, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind.), ECF No. 125-2 at ¶¶ 3–11.

57. In practice, therefore, covered entities instruct manufacturers to ship 340B covered outpatient drugs purchased at the 340B discount price to contract pharmacies, which then share in the "spread" generated by selling the drugs at higher prices to pharmacy customers and/or seeking

full commercial reimbursement from the patients' insurance plans. For-profit, commercial pharmacies thereby obtain significant profits from selling the 340B covered outpatient drugs that manufacturers must offer to covered entities at deeply discounted prices.

58. By dramatically expanding the pool of individuals who can access the drugs that covered entities can buy at discounted prices—including individuals who do not qualify as patients of the covered entity—covered entities and commercial pharmacies can obtain profits that extend far beyond Congress's intent when it created the 340B program. One study found that in 2018 alone, covered entities and their contract pharmacies generated more than $13 billion in estimated gross profits from the purchase of manufacturers' drugs at mandated 340B prices.

59. When commercial pharmacies are brought into the program, there is a significantly greater risk that manufacturers' discounted drugs will be dispensed to individuals who are not "patients" of the covered entity. As HHS has found, contract pharmacy arrangements "create complications in preventing diversion" (for example, contract pharmacies cannot verify patient eligibility in real-time like a covered entity can). HHS Office of Inspector General, OEI-05-13-00431, Mem. Report: Contract Pharmacy Arrangements in the 340B Program (2014) ("HHS Report"), at 1.

60. Because contract pharmacies often dispense 340B covered outpatient drugs from the same inventory as drugs dispensed to all other customers (and seek replenishment after the fact), the opportunities for unlawful distributions to ineligible patients increases, allowing covered entities and contract pharmacies to profit from the diversion that Congress intended to prohibit. *See* GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, at 28 (Sept. 2011) (noting that "approximately two-thirds of diversion findings in HRSA audits involved drugs distributed at contract pharmacies");

GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 35, 43–44 (June 2018) (finding 45% of covered entities that responded to a recent GAO survey admitted they do not provide any discount to patients who use their contract pharmacies; and many of the remaining 55% reported rarely giving discounts to patients obtaining medicines through contract pharmacies).

61. Covered entities and commercial pharmacies reap windfalls from gaining access to manufacturers' drugs at deeply discounted prices under the federal 340B program, but uninsured and underinsured patients are not benefitting. *See* HHS Report, at 2 (finding that "some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies"); Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, Wall. St. J. (Sept. 10, 2020) (explaining that "almost half the U.S. pharmacy industry now profits from the 340B program, which is designed as a narrow support to certain hospitals," while patients "don't benefit," even though manufacturers have "practically given the product away"); IQVIA Study, at 12 ("The 340B Drug Discount Program as it exists today is a complex system of arbitrage . . . in which most vulnerable patients at contract pharmacies do not get drug discounts."); Lin JK, et al., *Assessment of US Pharmacies Contracted with Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics*, JAMA Health Forum (2022), at 2 (finding that contract pharmacy growth from 2011–2019 was concentrated in affluent and predominantly White neighborhoods and that the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined).

62. While commercial pharmacies are driving massive growth in the 340B program—at double-digit annual rates—charity care by hospitals has decreased. Commentators have noted, for example, that as the 340B program has grown at a remarkable rate, the total value of hospitals'

uncompensated care has significantly declined. *See* Letter from Adam J. Fein to Hon. Lamar Alexander and Hon. Greg Walden in response to request for input on 340B drug pricing program (Oct. 30, 2020); Adam J. Fein, *340B Program Purchases Reach $24.2 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019).

63. Both the New York Times and Wall Street Journal have run exposés describing the flaws in contract pharmacy arrangements, flaws that enable large scale fraud and damage the very communities that the federal 340B program was designed to help. *See* Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, NY Times (Sept. 24, 2022) (describing how one 340B hospital "has been slashing services at Richmond Community while investing in the city's wealthier, white neighborhoods, according to more than 20 former executives, doctors and nurses"); *Anne Wilde Mathews* et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients.*, Wall Street Journal (Dec. 22, 2022) ("The data show that hospitals often extend their 340B discounts to clinics in well-off communities, where they can charge privately insured patients more than those on Medicaid" which "raise questions about the program's growth and purpose").

C. Manufacturers' Response to HRSA's Overreach

64. AbbVie and other manufacturers have exercised their lawful right to decline covered entity requests that manufacturers deliver or facilitate the delivery of their discounted 340B drugs to an unlimited number of commercial pharmacies.

65. AbbVie has implemented initiatives making clear that it will not indiscriminately accept requests that it transfer 340B discounted drugs to an unlimited number of third-party commercial contract pharmacies servicing hospital covered entities.

66. In implementing its initiatives, AbbVie has confirmed that it will continue to offer "each covered entity" the ability to "purchase" its covered outpatient drugs "at or below the applicable ceiling" price set by statute. 42 U.S.C. § 256b(a)(1). Moreover, if a hospital covered entity does not have an on-site pharmacy capable of dispensing to outpatients, it is permitted to designate one contract pharmacy location. AbbVie will facilitate bill to/ship to orders of 340B priced medicines to that location, provided that (1) the covered entity submits limited claims data on 340B utilization for such contract pharmacy location and (2) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site.

67. AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines, and out of which it can dispense AbbVie's discounted 340B drugs to qualifying patients. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

68. In addition to AbbVie, many other pharmaceutical manufacturers have adopted policies directed at addressing abuses of the 340B program by covered entities and contract pharmacies. Like AbbVie's, these policies do not refuse to supply drugs at discounted prices under the federal 340B program solely because the covered entity has an arrangement with a number of contract pharmacies; instead, they are directed at addressing program abuses.

D. Litigation in Federal Courts

69. HHS initially recognized that it lacked authority to compel manufacturers to transfer drugs to contract pharmacies. *See* Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (July 9, 2020). HHS then reversed its position and attempted to impose a new obligation on manufacturers.

70. On December 30, 2020, HHS issued a final decision—labeled an "Advisory Opinion"—that for the first time ever purported to require manufacturers to facilitate the transfer of their products to for-profit commercial pharmacies. *See* HHS, Advisory Opinion No. 20-06, Contract Pharmacies Under the 340B Program (Dec. 30, 2020). Various manufacturers brought suit in early 2021 to challenge this HHS decision.

71. On May 17, 2021, the government sent certain manufacturers "compliance" letters purporting to enforce the 340B statute, which stated that HHS had made a final determination that AbbVie had violated the 340B statute by not agreeing to transfer 340B discounted drugs to unlimited contract pharmacies.

72. While the December 30 decision was later withdrawn following a ruling from the federal district court for the district of Delaware, *see AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021), the May 2021 letters were not withdrawn.

73. Several cases brought by drug manufacturers challenging the May 2021 letters are pending on appeal before the D.C. and Seventh Circuits. *See Novartis Pharmaceuticals Corp. v. Johnson et al.*, No. 21-5299 (D.C. Cir.); *Eli Lilly & Co. v. U.S. Dep't of Health & Human Servs., et al.*, No. 21-3405 (7th Cir.).

74. Attorney General Landry filed amicus briefs on behalf of Louisiana in the Third and D.C. Circuit Courts of Appeals in support of HHS, expressing his disapproval of the manufacturers' policies. *See* Press Release, Attorney General Landry, *Defending Affordable Drug Prices, Attorney General Jeff Landry Joins Bipartisan, Nationwide Coalition* (May 16, 2022).

75. On January 30, 2023, the Third Circuit issued a decision recognizing that Congress intentionally "chose not to" impose delivery-related obligations on manufacturers, explaining that the federal 340B statute's plain text suggests that Congress intended "one-to-one transactions

between a covered entity and a drug maker without mixing in a plethora of pharmacies." *See Sanofi Aventis*, 2023 WL 1098017, at *4.

76. The Third Circuit further found that manufacturers' policies do not prevent covered entities from participating in the 340B program or entering into contractual relationships with commercial pharmacies. Under manufacturers' policies, covered entities "can still buy and dispense unlimited discounted drugs by having them delivered to an in-house or contract pharmacy." *Id*.

77. The Third Circuit rejected the argument that manufacturers were not permitted to address program abuses, such as diversion and duplicate discounting, by imposing restrictions on when they will transfer drugs to commercial pharmacies.

E. The Louisiana Law

78. On March 31, 2023, only two months after the Third Circuit's decision upholding the manufacturers' policies, Act 358 was introduced in the Louisiana House of Representatives. On June 12, 2023—long after the debate about the role of contract pharmacies in the federal 340B program had reached federal courts across the country—the Louisiana Legislature enacted Act 358, which it named the "The Defending Affordable Prescription Drug Costs Act."

79. The text of Act 358 makes clear that changing the terms of the federal 340B program is its regulatory object. Section 2882 defines the terms "340B drug" and "340B entity" by referencing 42 U.S.C. § 256b, the 340B statute. *See* La. Stat. Ann. § 40:2882(1), (2) ("Definitions."). In other words, the Louisiana statute cannot exist except in the context of the federal 340B program.

80. Act 358 contains two provisions that apply to pharmaceutical manufacturers: La. Stat. Ann. § 40.2882(A) and La. Stat. Ann. § 40.2882(B).

81. Section 40.2882(A) states: "A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services."

82. Section 40.2882(B) states: "A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity."

83. The statute cites no source, under the 340B statute or elsewhere, that permits Louisiana to add requirements to the conditions for participating in the federal 340B program, or that authorizes Louisiana to establish an enforcement process for the Attorney General to seek remedies for alleged violations of the federal 340B requirements.

84. "Interference" is not defined in the Chapter.

85. Section 40:2883 bars health insurance issuers, pharmacy benefit managers, and other third-party payors from reducing reimbursements and imposing certain conditions and requirements on 340B entities and 340B drugs based on their 340B status. *See* La. Stat. Ann. § 40:2883.

86. Section 40:2885 provides that a violation of Act 358 is a violation of the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Stat. Ann. 51:1401 *et seq.* A violation "subjects the violator to any and all actions, including investigative demands, remedies, and penalties provided for in the Unfair Trade Practices and Consumer Protection Law, except there shall be no right to bring private action pursuant to R.S. 51:1409." La. Stat. Ann. § 40:2885. "A violation occurs each time a prohibited act is committed." *Id.*

87. Under Louisiana's Unfair Trade Practices and Consumer Law, the Attorney General and district attorneys under his supervision may seek "a civil penalty against any person found by the court to have engaged in any method, act, or practice in Louisiana declared to be unlawful" under the statute. La. Stat. Ann. § 51:1407; 51:1417. The Attorney General and district attorneys may also seek injunctive relief for violations. La. Stat. Ann. § 51:1407. Courts can also issue "such additional orders or render judgments against any party, as may be necessary to compensate any aggrieved person for any property. . . which may have been acquired from such person by means of any method, act, or practice declared unlawful" and these orders can include restitution, revocation of licenses or other authority to conduct business, appointment of a receiver, dissolution of Louisiana corporate entities, and suspension or termination of foreign corporate entities' right to do business in Louisiana. La. Stat. Ann. § 51:1408.

88. Act 358 purports to limit its scope in Section 2886, titled "Federal preemption." It states that "[n]othing in this Chapter is to be construed or applied to be less restrictive than federal law for a person or entity regulated by this Chapter." La. Stat. Ann. § 40:2886. It further states that "[n]othing in this Chapter is to be construed or applied to be in conflict with any of the following: (1) Applicable federal law and related regulations [or] (2) Other laws of this state if the state law is compatible with applicable federal law." *Id.* It also states that "[l]imited distribution of a drug required under 21 U.S.C. 355-1 is not to be construed as a violation of this Chapter."

89. Despite stating that it should not be construed to conflict with federal law, there is no way to read Act 358 in congruence with the 340B statute. There is no role for states to regulate 340B pricing and the distribution of 340B priced drugs to entities permitted as a matter of federal law to participate in the federal program and obtain access to manufacturers' drugs at discounted

prices. The specific provisions of Act 358 conflict with Section 340B's requirements for drug manufacturers as well as its enforcement and penalty scheme.

STANDING

90. AbbVie is injured by Act 358 because it is subject to the Louisiana Attorney General's enforcement of the Act's requirements. Plaintiffs are signatories to 340B Pharmaceutical Pricing Agreements, and/or are successors-in-interest to executed 340 Pharmaceutical Pricing Agreements, with HRSA.

91. AbbVie's injuries are fairly traceable to Act 358 because the statute seeks to impose new state law obligations on drug manufacturers participating in the 340B program beyond those required by the federal statute. Neither section 340B, nor any existing regulation, nor the Pharmaceutical Pricing Agreement, contains these requirements. Moreover, the Act purports to grant the Louisiana Attorney General authority to enforce the Act in a way that violates federal law and would infringe on AbbVie's property rights.

92. AbbVie's injuries are fairly traceable to Act 358. As a result of Act 358, AbbVie is exposed to state enforcement actions and state remedies, including monetary penalties.

93. A favorable ruling is likely to address AbbVie's injuries. Enjoining the provisions of Act 358 that apply to pharmaceutical manufacturers or enjoining the enforcement of these provisions would redress AbbVie's injuries because AbbVie would not be exposed to state-imposed penalties for exercising its rights under the 340B program and the Constitution. Similarly, a declaratory judgment would redress AbbVie's injuries because AbbVie would not be exposed to enforcement actions and accumulating penalties.

BASIS FOR INJUNCTIVE RELIEF

94. Harm is irreparable "'if it cannot be undone through monetary remedies.'" *Paulsson Geophysical Servs., Inc. v. Sigmar*, 529 F.3d 303, 312 (5th Cir. 2008) (quoting *Enter.*

Int'l, Inc. v. Corporacion Estatal Petrolera Ecuatoriana, 762 F.2d 464, 472–73 (5th Cir. 1985)); *see also Janvey v. Alguire*, 647 F.3d 585, 600 (5th Cir. 2011) (affirming district court's issuance of preliminary injunction). Moreover, where costs are not recoverable because the government-defendant enjoys sovereign immunity from monetary damages, irreparable harm generally exists. S*ee Wages & White Lion Invs., LLC, v. United States Food & Drug Admin.*, 16 F.4th 1130, 1142 (5th Cir. 2021); *see also Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) ("The moratorium [on collecting rent during COVID-10 pandemic] has put the applicants, along with millions of landlords across the country, at risk of irreparable harm by depriving them of rent payments with no guarantee of eventual recovery.").

95. Forcing AbbVie to be subjected to state administrative enforcement proceedings that are preempted by and in conflict with federal law would impose irreparable harm on AbbVie. *See Texas v. Becerra*, 623 F. Supp. 3d 696, 736 (N.D. Tex. 2022) ("A procedural injury, by definition, is irreparable injury."), *appeal docketed*, No. 23-10246 (Mar. 10, 2023).

96. Moreover, if Act 358 is not enjoined as applied to AbbVie, AbbVie would be exposed to additional state law requirements as a condition of participating in the federal 340B program and would risk violating Act 358 simply by performing its federally mandated functions. A party may be irreparably injured in the face of the threatened enforcement of a preempted law." *Villas at Parkside Partners v. City of Farmers Branch*, 577 F. Supp. 2d 858, 878 (N.D. Tex. 2008) (citing *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992)); *see also Tex. Midstream Gas Servs., LLC v. City of Grand Prairie*, 608 F.3d 200, 206 (5th Cir. 2010) ("If a statute is expressly preempted, a finding with regard to likelihood of success fulfills the remaining [preliminary injunction] requirements."); *Louisiana v. Horseracing Integrity & Safety Auth. Inc.*, 617 F. Supp. 3d 478, 500 (W.D. La. 2022) ("The alleged conduct by [the federal agency] in

exceeding its authority given by Congress … constitute[s] irreparable injury."); *United States v. Texas*, 557 F. Supp. 3d 810, 821 (W.D. Tex. 2021) ("Because the United States has established a likelihood that the Order violates the Supremacy Clause, irreparable harm is presumed.").

97. If drug manufacturers such as AbbVie are required to deliver their drugs to contract pharmacies, the magnitude of the economic loss is beyond the capacity of Louisiana to compensate with damages. Discounted purchases under the program reached approximately $44 billion for fiscal year 2021. *See* HRSA, 2021 340B Covered Entity Purchases, https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases. The annual discretionary budget for Louisiana totals approximately $31 billion. *See State Budget Fiscal Year 2022-2023*, at 21, https://www.doa.la.gov/media/rxylnb4l/statebudget_fy23.pdf. The ordinary legal remedy of damages would be insufficient to cover AbbVie's losses. *See Eastern Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (plurality op.) (noting that the Supreme Court has considered injunctive relief where there is a "lack of a compensatory remedy").

98. Prospective injunctive relief is appropriate because of the ongoing nature of the infringement of constitutional rights resulting from Act 358. The law deprives AbbVie and other manufacturers of their federal rights under the actual terms of the 340B program. Act 358 threatens to impose significant penalties upon manufacturers if they do not capitulate to Louisiana's attempt to modify the terms of that federal program. And a taking occurs each and every time that a drug manufacturer is required against its own volition to transfer its drugs at the 340B discount price to a commercial pharmacy for the private benefit of that pharmacy. The deprivation of constitutional rights constitutes irreparable injury for purposes of a preliminary injunction. *Opulent Life Church v. City of Holly Springs, Miss.*, 697 F.3d 279, 395 (5th Cir. 2012) (citing Wright & Miller, Federal Practice and Procedure § 2948.1 n. 26 (2d ed. 1995) (collecting cases)); *Spring Tree Apartments,*

ALPIC v. Livingston Parish Council, 207 F. Supp. 2d 507, 515 (M.D. La. 2001) ("It has been repeatedly recognized by the federal courts that violation of constitutional rights constitutes irreparable injury as a matter of law.") (citing *Elrod v. Burns*, 427 U.S. 347 (1976)).

99. Granting injunctive relief here would not harm the State. It is well settled that the State has "no interest in enforcing a regulation that violates federal law." *Free Speech Coalition, Inc. v. Colmenero*, 2023 WL 5655712, at *29 (W.D. Tex. Aug. 31, 2023) (quoting *Alliance for Hippocratic Med. v. United States Food & Drug Admin.*, --- F.4th ---, 2023 WL 5266026, at *28) (5th Cir. Aug. 16, 2023) (granting preliminary injunction); *see also Louisiana v. Biden*, 55 F.4th 1017, 1035 (5th Cir. 2022) ("[t]here is generally no public interest in the perpetuation of unlawful agency action" (quoting *State v. Biden*, 10 F.4th 538, 560 (5th Cir. 2021))) (affirming district court's grant of preliminary injunction). Moreover, there is no evidence that uninsured and needy patients—in Louisiana or anywhere else—benefit from the use of contract pharmacies, and Louisiana has no legitimate interest in enriching commercial pharmacies at the expense of manufacturers and patients.

100. Granting injunctive relief would be in the public interest. The public has a strong interest in enforcing federal law and not permitting states to change the requirements for participation in federal healthcare programs. The public also has a strong interest in preventing states from imposing unconstitutional requirements that force the transfer of private property for the private benefit of private commercial parties.

FIRST CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Federal Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2

101. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

102. Under the Supremacy Clause of the Constitution, federal law is "supreme . . . , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. As a result, federal statutes enacted by Congress can preempt state law. *See, e.g.*, *Aldridge*, 990 F.3d at 874.

103. Preemption can take multiple forms: "Congress can expressly preempt state law in federal statutory language, or it can impliedly preempt state law." *Castro v. Collecto, Inc.*, 634 F.3d 779, 785 (5th Cir. 2011).

104. One type of implied preemption is field preemption, where federal law "is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation'" or where "the federal interest [in the field] is so dominant" that it "preclude[s] enforcement of state laws on the same subject[.]" *Id.* (quoting *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985)). Field preemption occurs where Congress intends "to foreclose any state regulation in the area, even if it is parallel to federal standards." *Arizona v. United States*, 567 U.S. 387, 401 (2012).

105. The 340B program is a comprehensive federal healthcare program. Every detail of the 340B program is determined by federal law, including which entities are eligible to participate in the program and the consequences for participating manufacturers who fail to comply with the 340B statute's requirements. The statute does not authorize state regulation concerning 340B pricing and who is entitled to access manufacturers' drugs at discounted 340B prices. It leaves no room for states to interfere with the carefully designed 340B program.

106. It is foundational constitutional law that States may not use their police power to regulate Congress's creations. *See McCullough v. Maryland*, 17 U.S. (4 Wheat.) 159 (1819) (Marshall, C.J.). A state law may not change the conditions for participation in the federal

Medicare and Medicaid programs. Any attempt by Louisiana to regulate in this area impermissibly changes the requirements for participating in the federal 340B program and nullifies the "natural effect" of federal law. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000).

107. Another type of implied preemption is conflict preemption. Conflict preemption occurs where it is impossible for a private party to comply with both state and federal law and also where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 372–73.

108. Act 358 purports to grant the Louisiana Attorney General a substantive role in the 340B program's administration and enforcement, despite and in conflict with the comprehensive compliance and enforcement regime Congress provided. The Louisiana Attorney General is not the entity Congress tasked with enforcement of the 340B statute. "Congress . . . made HHS administrator of the interdependent Medicaid Rebate Program and 340B Program." *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 120 (2011). State enforcement "would undermine the agency's efforts to administer these two programs harmoniously and uniformly." *Id.*

109. Congress not only defined who was entitled to administer the 340B program (the Secretary of HHS, who has lawfully delegated the authority to HRSA), it also delineated which tools were available to the Secretary to ensure compliance. The 340B statute defines which audit procedures and ADR mechanisms are available under the 340B program for handling disputes among manufacturers and covered entities concerning program compliance. *See* 42 U.S.C. § 256b(d)(l)(B)(v), (d)(3). Likewise, Congress outlined the penalties that apply to manufacturers who violate the statutory requirements under the 340B program and engage in "overcharging." *See* 42 U.S.C. § 256b(d)(l)(B)(vi), (d)(2)(B)(v). Act 358's attempts to install an alternative compliance and enforcement regime, with different regulators and distinct penalties, conflicts with

the procedures detailed in the 340B statute and the lawfully promulgated federal rules implementing the statute.

110. Louisiana also has no lawful authority to force manufacturers to transfer their drugs under the 340B program at deeply discounted prices to any entity, let alone commercial pharmacies that do not qualify as covered entities under the program. The carefully delineated obligation for manufacturers to offer 340B priced drugs to covered entities is lawfully imposed by federal law solely as a condition of a manufacturer's participation in federal healthcare programs. To the extent that Louisiana seeks to impose, through Act 358, any substantive obligation on manufacturers beyond what federal law requires, that state law obligation is preempted by federal law.

SECOND CLAIM FOR RELIEF

(In the Alternative)
Prospective Injunctive Relief and Declaratory Relief –
Violation of Takings Clause, U.S. Const. art. I, § 10, cl. 1

111. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

112. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend V.; *see also Chicago, Burlington & Quincy Ry. v. Chicago*, 166 U.S. 226 (1897) (incorporating and making applicable to states the Takings Clause of the Fifth Amendment through the Due Process Clause of the Fourteenth Amendment).

113. The Takings Clause extends to both real and personal property. *Horne v. Dep't of Agric.*, 576 U.S. 350, 358 (2015). It is not limited to instances when the government physically appropriates property for its own use through eminent domain. A taking can also occur through

legislation and regulation that sufficiently deprives a user of its property rights. *See E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998).

114. Under the Constitution, the government has no authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo v. City of New London*, 545 U.S. 469, 477 (2005) (explaining that "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation"). Such private takings are always unconstitutional, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005); *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) ("[i]t is against all reason and justice" to allow government to "take[] property from A. and give[] it to B").

115. "Whenever a regulation results in a physical appropriation of property, a per se taking has occurred." *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021). Statutes or regulations that mandate the physical transfer of personal property from one private party to another private party amount to an unconstitutional taking with or without just compensation.

116. Act 358 appropriates AbbVie's property rights in its drugs for the private benefit of for-profit, commercial pharmacies. If Louisiana requires manufacturers to deliver their drugs to other private entities at below-market prices—by purporting to add that as a state-law obligation attached to the federal 340B scheme—then Louisiana is engaged in an impermissible per se violation of the Constitution's Takings and Due Process Clauses.

117. In the alternative, Act 358 effectuates a partial regulatory taking.

118. In *Penn Central Transportation Corp. v. New York City*, 438 U.S. 104, 124 (1978), the Supreme Court recognized that a regulatory taking requires consideration of a flexible three-factor test: (1) the economic impact of the regulation, (2) the extent to which the regulation has

interfered with investment backed expectations, and (3) the "character of the governmental action."

119. Act 358's purported requirement that manufacturers transfer their drugs to commercial pharmacies is constitutionally impermissible because it imposes significant financial losses on AbbVie and other manufacturers, interferes with drug manufacturers' reasonable investment backed expectations, and serves no valid government purpose because it deprives manufacturers of the full use and control of their property on a continual basis for the commercial benefit of private parties.

THIRD CLAIM FOR RELIEF

Prospective Injunctive Relief and Declaratory Relief – Violation of the Right to Property, La. Const. Ann. art. I, § 4.

120. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

121. The Louisiana Constitution, like the Federal Constitution, requires the government to have a public-use purpose for any taking of private property and to provide just compensation. *See Magee v. W. Jefferson Levee District*, 17-294 (La. App. 5 Cir. 12/13/17), 235 So. 3d 1230. Louisiana law recognizes that a governmental regulation can constitute a taking. *City Bar, Inc. v. Edwards*, 2021-1437 (La. App. 1 Cir. 8/30/22), 349 So. 3d 22, 30, writ denied, 2022-01475 (La. 11/22/22), 350 So. 3d 498, reconsideration not considered, 2022-01475 (La. 2/7/23), 354 So. 3d 661.

122. A violation of the Louisiana Constitution's Taking Clause is self-executing, and as a result, a cause of action arises when the State commits a taking without justly compensating the victim. *City Bar, Inc. v. Edwards*, 2021-1437 (La. App. 1 Cir. 8/30/22), 349 So. 3d 22, 30, writ

denied, 2022-01475 (La. 11/22/22), 350 So. 3d 498, reconsideration not considered, 2022-01475 (La. 2/7/23), 354 So. 3d 661.

123. Louisiana has carefully delineated the definition of "public purpose" in Article 4 of its Constitution Enumerated public purposes include: (1) a general public right to a definite use of the property; (2) continuous public ownership of property dedicated to one or more of the following objectives and uses: (a) public buildings in which publicly funded services are administered, rendered, or provided (b) roads, bridges, waterways, access to public waters and lands, and other public transportation, access, and navigational systems available to the general public (c) drainage, flood control, levees, coastal and navigational protection and reclamation for the benefit of the public generally, (d) parks, convention centers, museums, historical buildings and recreational facilities generally open to the public, (e) public utilities for the benefit of the public generally, (f) public ports and public airports to facilitate the transport of goods or persons in domestic or international commerce; and, lastly, (3) the removal of a threat to public health or safety caused by the existing use or disuse of the property.

124. Act 358 does not allege or serve any recognized public purpose.

125. It is unconstitutional in Louisiana for the government to take the property of one private party and transfer it to another private party. As the Attorney General explained in Opinion No. 07-0147, "many state legislatures—Louisiana's among them—quickly moved to enact state-level protections against the taking of private property for private purposes" following the United States Supreme Court's decision in *Kelo v. City of New London*, 545 U.S. 469 (2005). In other words, in the absence of a § 4 "public purpose," "it is the opinion of this Office that expropriated property may not be sold to private interests." La. A.G. Op. No. 07-0147. When the sole purpose

of a taking is initiating the transfer of property from one private party to another is an unconstitutional taking. *See id.*

126. As alleged above, to the extent not preempted by federal law, Act 358 purports to require manufacturers to transfer their drugs to commercial pharmacies, and in doing so, Act 358 deprives the manufacturers of the full use of their property. Act 358 does not—and indeed does not even attempt to—articulate any acceptable public purpose for this transfer of property and cannot be justified by any public purpose authorized by Louisiana law. As a result, Act 358 seeks to take property from one private party and transfer it to another in violation of the Louisiana Constitution.

FOURTH CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Due Process Clause, U.S. Const. art. XIV

127. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

128. The Due Process Clause of the Fourteenth Amendment provides that no State may "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1.

129. A statute is unconstitutionally vague if persons "of common intelligence must necessarily guess at [its] meaning and differ as to [its] application." *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411, 421 (5th Cir. 2001) (citation omitted). "In the civil context, 'the statute must be so vague and indefinite as really to be no rule at all.'" *Groome Res. Ltd., L.L.C. v. Par. of Jefferson*, 234 F.3d 192, 217 (5th Cir. 2000) (internal quotation marks and citation omitted). However, "where a statute permits 'potentially significant civil and administrative penalties, including fines and license revocation,' quasi-criminal treatment is appropriate and thus the more strict standard of review applies." *Ford Motor Co. v. Texas Dep't of Transp.*, 264 F.3d 493, 508

(5th Cir. 2001) (quoting *Women's Med. Ctr.*, 248 F.3d at 422). A quasi-criminal statute must define its terms "'with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement.'" *United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122 (5th Cir. 1991) (quoting *Kolender v. Lawson*, 461 U.S. 352, 357 (1983)).

130. Act 358's provisions that prohibit a manufacturer's "interfere[nce]" with a pharmacy contracted are unconstitutionally vague and do not provide drug manufacturers with fair notice as to what conduct is actually prohibited.

131. "Interference" is not defined in Act 358. The meaning of the word is especially ambiguous given that the Third Circuit and multiple federal district courts have confirmed that drug manufacturers' policies imposing reasonable conditions on the provision and delivery of 340B drugs to contract pharmacies are lawful under Section 340B (yet such policies are prohibited under Act 358).

132. And "pharmacy" is defined, by cross-reference to include not only pharmacies located in Louisiana but also includes "any place outside of [Louisiana] where drugs are dispensed and pharmacy primary care is provided to residents of [Louisiana]" if the "residents who are provided pharmacy care [are] physically located in [Louisiana]." La. Stat. Ann. § 37:1164(38); La. Rev. Stat. § 40:2882 ("Pharmacy" has the same meaning as defined in R.S. 37:1164(38) except that residents who are provided pharmacy care shall be physically located in this state."); La. Stat. Ann. § 37:1164(38) ("Pharmacy" means any place located within this state where drugs are dispensed and pharmacy primary care is provided, and any place outside of this state where drugs are dispensed and pharmacy primary care is provided to residents of this state."). Because the application of Act 358 may theoretically apply to all pharmacies nationwide if a Louisiana resident

is provided drugs or pharmacy care at that pharmacy, manufacturers have no way of predicting or understanding the scope of Act 358's prohibition on "interference."

133. To the extent Act 358 is not preempted and does not unconstitutionally appropriate AbbVie's property for private use, then it is unconstitutionally vague on its face. The provisions prohibiting manufacturers from "interfering" with contract pharmacies fails to provide fair notice as to what is prohibited. Persons of common intelligence must guess at its meaning and may well offer vastly different yet reasonable interpretations of its scope. This is especially concerning given the quasi-criminal penalties of the act and its potential to reach speech as well as conduct.

PRAYER FOR RELIEF

WHEREFORE, AbbVie prays for the following relief:

a. A declaration, order, and judgment holding Act 358 unlawful because it is preempted by federal law and unconstitutional under the Supremacy Clause;

b. A declaration, order, and judgment declaring that Act 358 effects an impermissible taking of AbbVie's property for private benefit;

c. A declaration, order, and judgment declaring that Act 358 violates the Due Process Clause;

d. A declaration, order, and judgment holding that the 340B statute does not require drug manufacturers to provide 340B pricing to contract pharmacies or transfer or cause their discounted covered outpatient drugs to be transferred to contract pharmacies;

e. A preliminary and permanent injunction enjoining the Louisiana Attorney General from enforcing Act 358;

f. An award of all costs and attorneys' fees pursuant to any applicable statute or authority; and

g. Any other relief that this Court deems just and proper.

Dated: September 27, 2023

Respectfully submitted,

/s/ Charles M. Jarrell

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